

Folitex[®] Earloop plus

MOUTH AND NOSE COVERING MASK WITH ELASTIC EAR LOOPS FOR MEDICAL USE
TECHNICAL DATA



PRODUCT CLASSIFICATION

Medical Device Class I

QUALITY CERTIFICATES

ISO 9001, ISO 13485

APPLIED STANDARDS

EN 14683, ISO 22609, ISO 10993

INTENDED USE

ACC. EN 14683:2019

The main intended use of medical face masks is to protect the patient from infective agents and, additionally, in certain circumstances to protect the wearer against splashed or potentially contaminated liquids. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.

MANUFACTURER



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IMPORTER



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MEDICAL DEVICE INFORMATION	Medical device class I, EN 14683      	
MASK DESIGN	Colour Layers Fixation	white (inner side) blue (outer side) 3ply, folded, ultrasonically welded elastic ear loops, flexible nose clip
MATERIAL	Outer layer Filter layer Inner layer Nose clip Ear loops	spunbond polypropylene, blue melt-blown polypropylene spunbond polypropylene, white aluminum strip spandex/polyester Free of natural rubber latex
PHYSICAL PROPERTIES	Protection type Barrier efficiency Breathability Splash resistance Microbial cleanliness	type IIR ≥ 98 % bacterial filtration efficiency BFE < 60 Pa/cm ² differential pressure for air permeation withstanding penetration of artificial blood at a pressure of ≥ 16 kPa ≤ 30 CFU/g (colony forming units)
DIMENSIONS	Mask Earloop Nose Fixation	175 mm width/95 mm height 120 mm length 130 mm length
LOGISTIC INFORMATION	REF Dispenser pack Transportation carton Storage conditions	6073317 50 pieces 185 x 100 x 100 mm (L x W x H) 10 dispenser packs 520 x 210 x 195 mm (L x W x H) protect from direct heat, lighting or sunlight/UV radiation, store clean and dry at ambient temperature